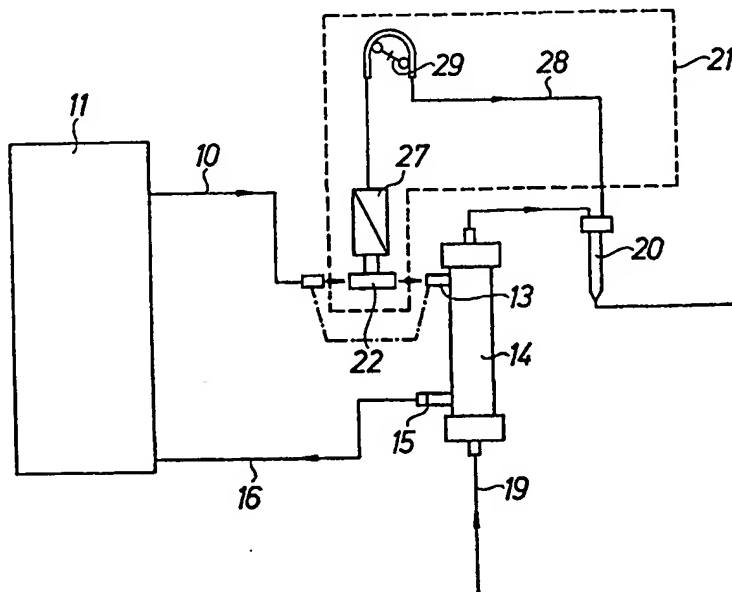




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61M 1/14, 1/34</b>		<b>A1</b>	(11) International Publication Number: <b>WO 98/16269</b>
			(43) International Publication Date: 23 April 1998 (23.04.98)
(21) International Application Number: PCT/SE97/01049 (22) International Filing Date: 13 June 1997 (13.06.97) (30) Priority Data: 9602329-6                      13 June 1996 (13.06.96)                      SE (71) Applicant (for all designated States except US): ALTHIN MEDICAL AB [SE/SE]; P.O. Box 39, S-372 21 Ronneby (SE). (72) Inventors; and (75) Inventors/Applicants (for US only): FALKVALL, Thore [SE/SE]; Thorildsgatan 2, S-254 40 Helsingborg (SE). CARLSSON, Per-Olov [SE/SE]; Morkullevägen 11, S-280 10 Sösdala (SE). SANDBERG, Lars-Olof [SE/SE]; Serpentinvägen 33, S-372 31 Ronneby (SE). (74) Agents: STRÖM, Tore et al.; Ström & Gulliksson AB, P.O. Box 4188, S-203 13 Malmö (SE).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  Published With international search report. In English translation (filed in Swedish).	

(54) Title: DISPOSABLE HEMODIAFILTRATION SET



## (57) Abstract

A sterile disposable hemodiafiltration set to be connected to a dialysis machine comprising a dialyzer (14) with an extracorporeal blood path (19) and a supplying dialysis liquid supply line (10) which can be connected to the dialyzer. The hemodiafiltration set comprises a sterilized unit consisting of a hose connection (28) with a sterile filter (27) therein, said hose connection being arranged for connection at one end thereof to the extracorporeal path (19) via a separate pump (29; 30) and being provided with a three-way joint (22) at the other end thereof for connection of said latter end between the dialysis liquid supply line (10) and the dialyzer (14).

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

### Disposable hemodiafiltration set

The invention relates to a sterile disposable hemo-  
5 diafiltration set to be connected to a dialysis machine  
comprising a dialyzer with an extracorporeal blood path and  
a dialysis liquid supply line, which can be connected to  
the dialyzer.

In the conventional hemodialysis treatment impurities  
10 are separated from the blood in the dialyzer by diffusion  
while the separation of impurities in hemodiafiltration  
treatment is effected both by diffusion and by convection  
dialysis liquid being supplied as a substitute liquid to  
the blood in the extracorporeal path. Hemodiafiltration  
15 treatment is preferred because also greater molecules are  
separated from the blood; greater molecules cannot be sepa-  
rated to the same extent when the dialysis treatment  
includes diffusion only. The dialysis liquid to be supplied  
to the blood as the substitute liquid is of course subject  
20 to higher demands as to sterility than dialysis liquid  
passing through the dialyzer and, therefore, it undergoes  
supplementary filtering before being supplied to the blood  
path.

US-A-4 702 829 describes a machine for hemodiafiltra-  
25 tion wherein the dialysis liquid to be used as substitute  
liquid is passed through two sterile filters provided in  
the machine which are not used for filtering the dialysis  
liquid to be supplied to the dialyzer. Having passed the  
sterile filters the substitute liquid is passed through a  
30 disposable line section including a microfilter and being  
connected to the blood path either on the outlet side of  
the dialyzer (post-dilution) or on the inlet side of the  
dialyzer (pre-dilution).

In the dialysis machine intended for hemodiafiltra-  
35 tion according to US-A-4 702 829 as in other dialysis  
machines on the market, intended for hemodiafiltration

there is provided on the machine a separate outlet for substitute liquid to which a disposable set forming part of the hemodiafiltration circuit is connected in order to set up the dialysis machine for hemodiafiltration treatment, said circuit being partly permanent and exposed to disinfection between the treatments in the dialysis machine especially constructed for hemodiafiltration.

Taking into account that the dialyzer always is connected to the dialysis machine via hoses by quick connectors (Hansen connectors) the object of the invention is to provide a disposable set which can be easily connected to any dialysis machine constructed for hemodialysis and having ultrafiltration control but in no way constructed or prepared for hemodiafiltration treatment, in order to allow that the dialysis liquid to be supplied to the dialyzer is partly drained off and after filtration in a sterile microfilter included in the disposable set, is supplied to the blood path.

In order to achieve said object the disposable set of the kind referred to above has obtained according to the invention the characterizing features of claim 1. By this arrangement it is possible to make dialysis liquid available on any dialysis machine constructed for hemodialysis and having ultrafiltration control simply by disconnecting the dialyzer from the dialysis liquid and supply line and interconnecting the three-way joint between the supply line and the dialyzer the dialysis liquid after filtration in the sterile filter being supplied via the hose connection to the blood path at one side or the other of the dialyzer (pre-dilution or post-dilution, respectively).

According to a preferred embodiment of the invention the sterile filter is combined with the three-way joint and forms an integral unit therewith.

In order to explain the invention in more detail reference is made to the accompanying drawings disclosing an illustrative embodiment and wherein

FIG. 1 is a diagram of a dialysis machine constructed for hemodialysis and having ultrafiltration control with the disposable set according to the invention in one embodiment thereof,

FIG. 2 is a corresponding diagram of a dialysis machine with a disposable set of a second embodiment,

FIG. 3 is a perspective view of a three-way joint forming part of the disposable set, and

FIG. 4 is a perspective view of a three-way joint made integral with a sterile filter.

In FIG. 1 a dialysis machine constructed only for hemodialysis and having ultrafiltration control indicated by a block 11. The machine supplies dialysis liquid of high quality in a line 10 which is connected to the dialysis liquid inlet 13 of a dialyzer. The dialysis liquid outlet 15 thereof is connected to an outlet line 16. An extracorporeal blood path 19 extends through the dialyzer 14 and includes a drip chamber 20.

In order to allow hemodiafiltration treatment by using the dialysis machine with the system described the invention provides a sterile disposable hose set located within the dash line frame 21. This disposable hose set comprises a three-way joint 22 of the kind disclosed in FIG. 3. The three-way joint comprises a socket 23 with quick connectors at both ends thereof, so called Hansen connectors, one connector 24 thereof being a male connector to be connected with supply line 10, and the other connector 25 being a female connector to be connected with inlet 13 for dialysis liquid of the dialyzer 14. The inlet is provided with a male connector and the supply line with a female connector, and in conventional hemodialysis treatment these two connectors are interconnected as indicated

by a dot-and-dash line, but when a hemodiafiltration treatment shall take place the connectors are disconnected and socket 23 of the three-way joint is interconnected therebetween. The three-way joint also has a branch socket 26 and  
5 is connected at this socket with a sterile filter 27 which is connected to one end of a hose 28. The hose set is delivered in a sterile package. After the three-way joint has been connected as explained above the other end of hose 28 is connected to drip chamber 20 and the hose is placed  
10 around the rotor of a peristaltic pump 29.

From the flow of dialysis liquid supplied to the dialyzer a flow determined by the peristaltic pump thus is drained off, and after filtration in the microfilter this flow is supplied to the drip chamber to be supplied to the  
15 blood in the extracorporeal blood path during a hemodiafiltration treatment. The supply can take place at another site either for post-dilution, as shown, or for pre-dilution.

In a preferred development of the invention the sterile filter 27 is integrated with the three-way joint 22 as  
20 shown in FIG. 4. The filter can instead be integrated with another element in the circuit for substitute flow for example with the drip chamber 20.

In the embodiment according to FIG. 2 the peristaltic  
25 pump is replaced by a pump - indicated by a symbol 30 - which is combined with the unit formed by the three-way joint 22 and the sterile filter 27. The pump is connected with a turbine which is driven by the dialysis liquid flow to the dialyzer 14, to pump substitute liquid to the extra-  
30 corporeal path via the sterile filter.

Summarizing, the invention provides the possibility of effecting by means of an ultrafiltration controlled dialysis machine, constructed for hemodialysis only and not constructed or prepared for hemodiafiltration treatment, a  
35 hemodiafiltration treatment without performing any modifi-

cation in the machine or the program thereof. In other words, no machine of special construction is necessary for hemodiafiltration.

## CLAIMS

1. A sterile disposable hemodiafiltration set to be connected to a dialysis machine comprising a dialyzer (14) with an extracorporeal blood path (19) and a dialysis liquid supply line (10) which can be connected to the dialyzer characterized in that the hemodiafiltration set comprises a sterilized unit consisting of a hose connection (28) with a sterile filter (27) provided therein said hose connection being arranged for connection at one end thereof to the extracorporeal path (19) via a separate pump (29; 30) and being provided with a three-way joint (22) at the other end thereof for connection of said latter end between the supply line (10) for dialysis liquid and the dialyzer (14).

2. Hemodiafiltration set according to claim 1, characterized in that the three-way joint (22) is provided with quick connectors (24, 25) for connection to matching quick connectors on the dialysis liquid supply line (10) and the dialyzer (14), respectively.

3. Hemodiafiltration set according to claim 1 or 2, characterized in that the three-way joint (22) and the sterile filter (27) are integrated to form a unit.

4. Hemodiafiltration set according to any of claims 1 to 3, characterized in that the hose connection forms a liquid conducting element in a peristaltic pump (29).

5. Hemodiafiltration set according to any of claims 1 to 3, characterized in that the pump (30) is integrated with the three-way joint to form a unit therewith.



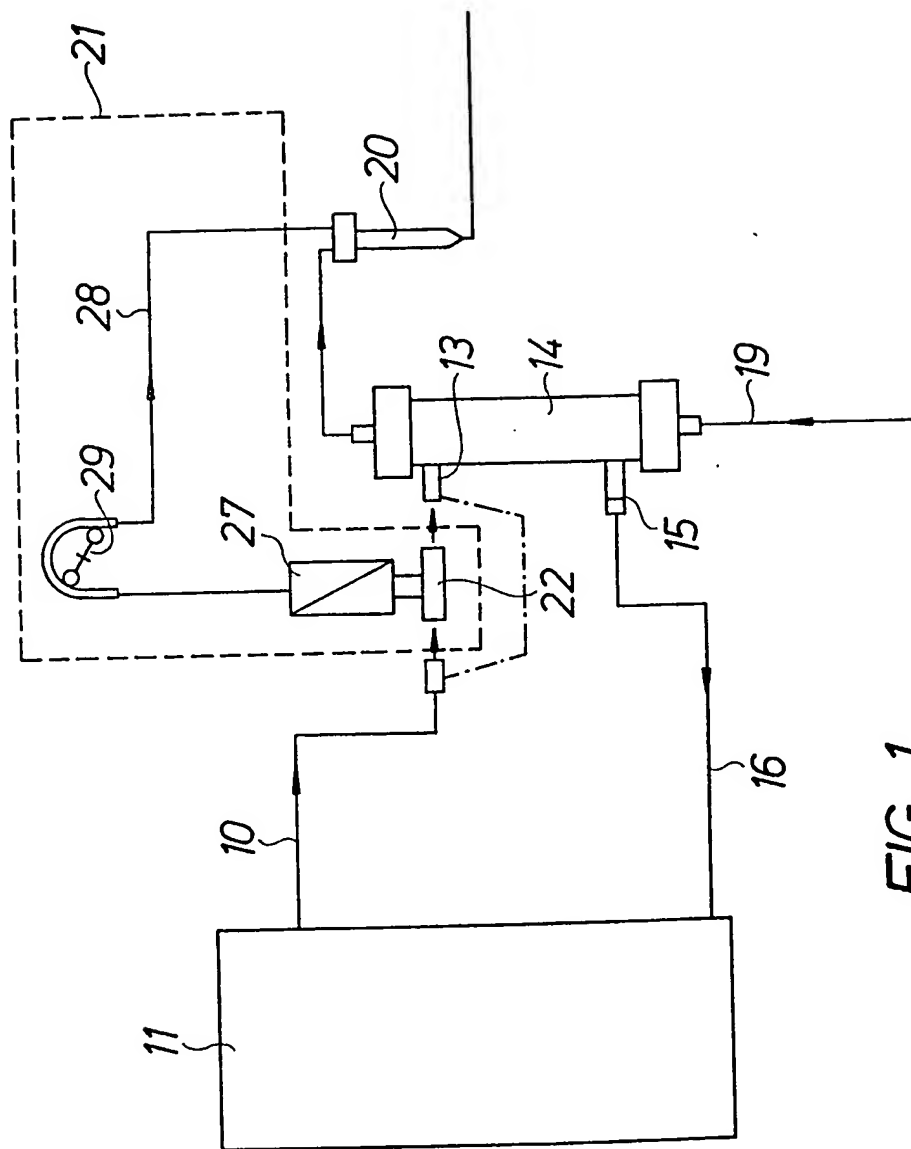


FIG. 1

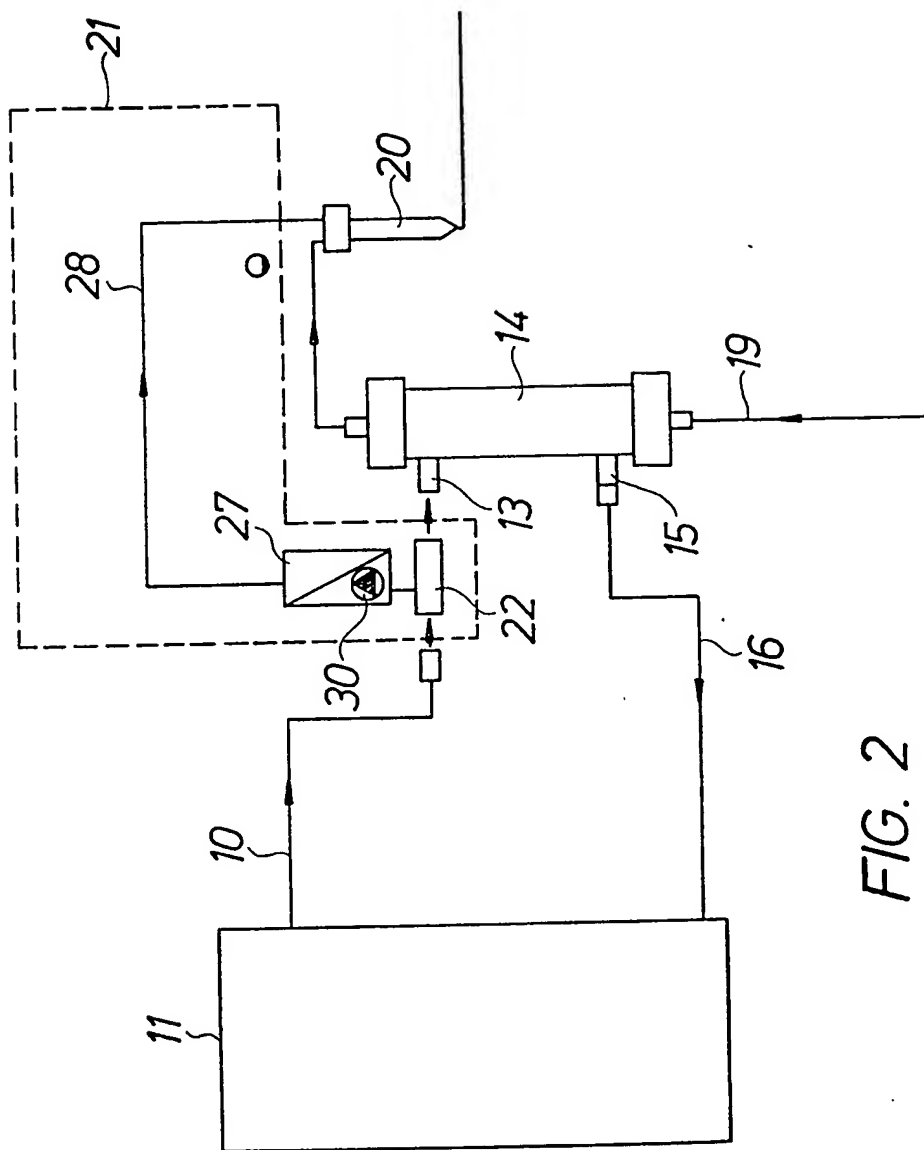


FIG. 2

3/3

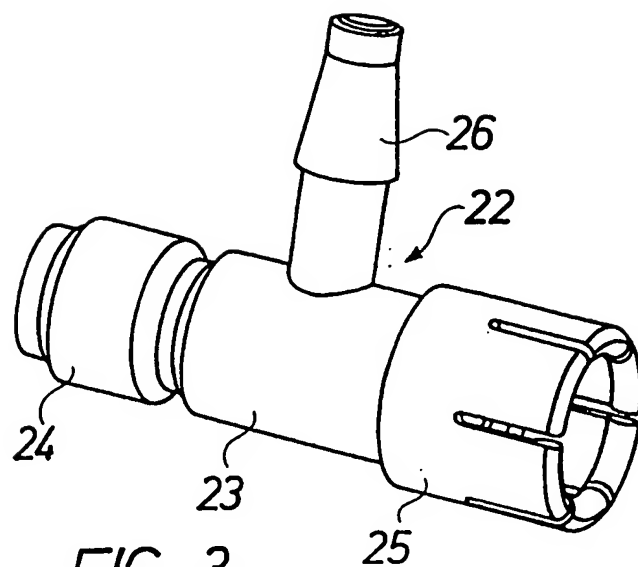


FIG. 3

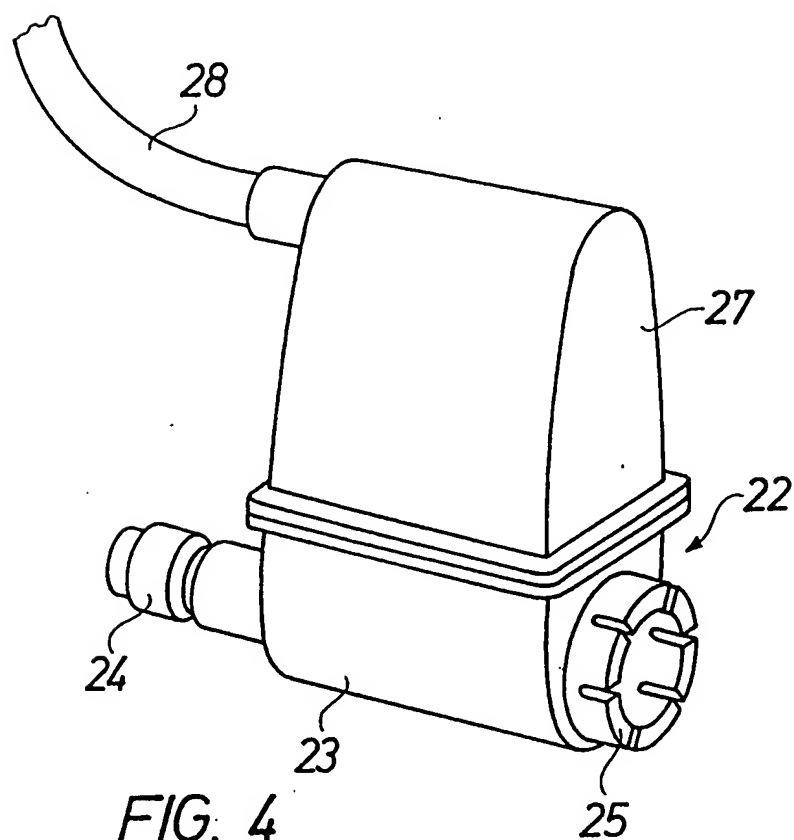


FIG. 4

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01049

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 1/14, A61M 1/34

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4702829 A (HANS-DIETRICH POLASCHEGG ET AL.), 27 October 1987 (27.10.87), column 6, line 26 - line 50 --	1-5
A	US 5490925 A (HANS-GÜNTEREIGENDORF), 13 February 1996 (13.02.96), column 4, line 23 - line 44 -- -----	1-5

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

23 Sept 1997

Date of mailing of the international search report

26 -09- 1997

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Eva Selin

Telephone No. +46 8 782 25 00

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

01/09/97

International application No.

PCT/SE 97/01049

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4702829 A	27/10/87	DE 3444671 A,C	12/06/86
		DE 3448262 C	21/06/90
		EP 0189561 A,B	06/08/86
		JP 1869060 C	06/09/94
		JP 61203973 A	09/09/86
US 5490925 A	13/02/96	DE 4208274 C	21/10/93
		EP 0560368 A	15/09/93
		EP 0720856 A	10/07/96
		US 5259961 A	09/11/93